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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,497	07/24/2006	Yasuhiko Tabata	17195/006001	4614

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EXAMINER	
STOICA, ELLY GERALD	
ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,497	TABATA ET AL.	
	Examiner	Art Unit	
	Elly-Gerald Stoica	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/29/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

1. Claims 1-5 are pending in the application.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

The claims are drawn to a cardiomyopathy therapeutic agent that contains hepatocyte growth factor (HGF) and gelatin hydrogel, and gradually releases HGF, wherein cardiomyopathy is hypertrophic cardiomyopathy, idiopathic cardiomyopathy, primary cardiomyopathy or secondary cardiomyopathy.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to:

1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation

needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

While the specification is enabling for the HGF containing gel to be used to treat dilatory cardiomyopathy in an animal model, it does not provide direction from inventor to be used to treat hypertrophic cardiomyopathy, idiopathic cardiomyopathy, primary cardiomyopathy or secondary cardiomyopathy. There is no working example for these particular conditions and the art, at the time that the invention was made has few teachings with respect to the use of the HGF gel containing therapies of the conditions mentioned. Therefore, in order to ascertain if the Invention is useful for treating cardiomyopathies other than dilatory cardiomyopathy undue experiments would be necessary.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1-5 are rejected under 35 U.S.C. 102(a) as being anticipated by Tambara et al.(Circulation, 106, supplement, p II-350, Nov., 2002, Meeting abstract)).

The claims are drawn to a cardiomyopathy therapeutic agent that contains hepatocyte growth factor (HGF) and gelatin hydrogel, and gradually releases HGF.

Tambara et al. teach a controlled release of HGF via gelatin hydrogel sheets that, in a rat model of dilated cardiomyopathy, improves left ventricular function. Since the Office does not have laboratory facilities to check if the gel used in the experiment has the same properties as the gelatin described in claim 2, it is considered that the properties of the gelatin of Tambara et al. are the same to the gelatin claimed. This assumption is strengthened by the fact that the Applicants are part of the co-authors of the prior art communication. Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Regarding intended use of a composition, the Office gives patentable weight only insofar as it affects the agent per se. Since the composition is the same, the intended use, be it dilation cardiomopathy, hypertrophic cardiomyopathy, idiopathic cardiomyopathy, primary cardiomyopathy or secondary cardiomyopathy does not constitute patentable subject matter and is considered anticipated by the prior art reference.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tabata et al. (EP 0702959A1, 03/27/1996) in view of Kmiecik et al. (U. S. Pat. 5,362,716).

The claims are drawn to a cardiomyopathy therapeutic agent that contains hepatocyte growth factor (HGF) and gelatin hydrogel, and gradually releases HGF, wherein cardiomyopathy is dilation cardiomyopathy, hypertrophic cardiomyopathy, idiopathic cardiomyopathy, primary cardiomyopathy or secondary cardiomyopathy. The gel is an acidic gelatin obtained by alkaline treatment of collagen and has a molecular weight between 100-200 kDa and zeta potential in aqueous solutions of –15 to –20 mV. Regarding intended use of a composition see supra.

Tabata et al. (supra), teach various cross-linked gelatin preparations with methods that are mentioned in the instant application (p.3, line 15 to p. 4 line 40, Examples 1-10)). The gel incorporates a growth factor (bFGF) and is designed to ensure a controlled and persistent release of the growth factor in vivo activity (p.18, line 54 to p.19, line 2). Tabata et al does not teach the use of HGF in gels.

Kmiecik et al. teach the use of HGF in soft-agar growth assay in bone marrow cells (Example VI) thus demonstrating the mobility of HGF in cross-linked matrices.

It would have been obvious for a person of ordinary skill in the art at the time that the invention was made to have used the gel composition of Tabata to incorporate HFG as a growth factor as taught by Kmiecik et al. to deliver it to targets with a reasonable expectation of success. The motivation to do so would have been offered by Tabata et al. that demonstrated the beneficial effects of continued release of growth factors.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1 and 2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3 of copending Application No. US 2006/0148691. Although the conflicting claims are not identical, they are not patentably distinct from each other because they contain a gelatin hydrogel that may contain HGF as an angiogenic factor. The products being identical, the intended use is not given patentable weight.

Claims 1 and 2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 6 of copending Application No. US 2006/0183680. Although the conflicting claims are not identical, they are not patentably distinct from each other because they contain a gelatin hydrogel that may contain HGF as a vascularization induction factor.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elly-Gerald Stoica whose telephone number is (571) 272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LORRAINE SPECTOR
PRIMARY EXAMINER